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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,302	06/05/2001	Robert F. Rioux	MIY-P01-011	7588
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FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER THANH, QUANG D	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/874,302	<b>Applicant(s)</b> RIOUX, ROBERT F.	
	<b>Examiner</b> Quang D. Thanh	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2006 and 09 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/14/05; 10/16/06</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse in the reply filed on 4/9/07 is acknowledged. Applicant's arguments, see pages 2-3, filed on 4/9/07, with respect to restriction requirement have been fully considered and are persuasive. Accordingly, the restriction requirement of claims 1-2, 4, 6-9, and 11-19 has been withdrawn.
2. This office action is responsive to the amendment filed on 12/13/06. As directed by the amendment: claims 4 and 13 have been amended, claims 3, 5 and 10 have been cancelled, and new claim 19 has been added. Thus, claims 1-2, 4, 6-9 and 11-19 are presently pending in this application.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 4, 7, 8, 13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Re claims 4, 13 and 16, the phrase "may be" renders the claim indefinite because it is unclear whether a suture or a sling is introduced into the window or not ?
6. Claims 7 and 8 recite the limitation "the shielding mechanism". There is insufficient antecedent basis for this limitation in the claims.

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7. Re claim 7, the phrase "the pair of proximal tabs being adapted **to undo** the shielding mechanism so as to expose the implant" is unclear as to how these proximal tabs could undo the shield. It is suggested to replace with -- the pair of proximal tabs being adapted to bend inward to drive outward the shield so as to expose the implant from the shield --

8. Re claim 8, the limitation "the implant" has not been positively recited in claim 1, therefor it is not clear whether this implant is part of the preamble recited in claim 1 or is a structural element that is part of the device.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 4, 6, 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Benderev et al. (5,439,467).

11. Re claims 1-2, 4 and 6, Benderev discloses a surgical instrument (fig. 1 and 1a) for treating female urinary incontinence, the instrument comprising: a) a handle 110 (fig. 1); b) a shaft 125 extending in a distal direction from the handle and comprising a curved portion (fig. 1a, col. 5, lines 6-9), the shaft being adapted to access interior tissue within a human body; c) a blunt tip 140 (col. 5, lines 12-17) disposed at a distal end of the shaft 125 (fig. 2) for blunt dissection of tissue; and d) a window 130 (fig. 4)

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including an L-shaped slot located within a distal end portion of the shaft, the L-shaped slot including a first leg 132C (fig. 4) extending radially inward and a second leg 131A (fig. 4) extending axially in a distal direction from an inner end of the first leg; wherein the shaft is adapted to transvaginally access interior tissue within a female human body (col. 7, lines 1-4); wherein a suture may be introduced into the window and retained by the window; wherein the handle 110 comprises a friction based gripping surface (col. 4, lines 57-59).

12. Re claims 11-16 and 19, Benderev discloses an element 115 for covering the window 130 (fig. 4); an actuator 122 (fig. 1) for operating the element, the element being movable between an open position, an intermediate position, and a closed position (fig. 4, col. 6, lines 28-37); wherein a suture 165 (fig. 2) may be introduced into the window when the element is in placed in the open position, a suture may be retained by the window when the element is placed in the intermediate position, and a suture may be released from the window when the element is placed in the closed position; wherein the actuator comprises a knob 156 (fig. 1, col. 5, lines 49-52) located on the handle; wherein the element comprises a cutting edge 120 (fig. 2); wherein the first leg 132C and the second leg 132A form an angle of about 90 degrees (fig. 4).

13. With respect to the functional languages in claims 17-18, Benderev's device is capable of performing the claimed functions.

### ***Double Patenting***

14. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. Claims 7-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15-17 filed on 3/13/06 of copending Application No. 10/973,191. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-2, 4, 6 and 11-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-14 and 18-20 of copending Application No. 10/973,191. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims have the same scope and elements.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

18. Applicant's arguments filed on 12/13/06 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (571) 272-4982. The examiner can normally be reached on Monday-Thursday & alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The Central FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for all communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Quang D. Thanh/

Quang D. Thanh, Primary Examiner  
Art Unit 3771, (571) 272-4982